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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/998,880	10/31/2001	E. Skott Greenhalgh	24426-A USA	7282

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EXAMINER

NAFF, DAVID M

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 03/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/998,880	Applicant(s) GREENHALGH ET AL.	
	Examiner David M. Naff	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 14-21 is/are pending in the application.
- 4a) Of the above claim(s) 21 and 30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 14-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/20/04</u> . | 6) <input type="checkbox"/> Other: _____ |

✓

DETAILED ACTION

An amendment of 12/16/04 amended claims 1, 4, 10, 11 and 15, and canceled claim 13.

Claims 20 and 21 are withdrawn from further consideration
5 pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 7/19/04.

Claims 1-12 and 14-19 are examined on the merits.

The text of those sections of Title 35, U.S. Code not included in
10 this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 1-12 and 14-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not
15 described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses only a supported lattice where the interstices formed by the flexible filamentary members are smaller
20 than the interstices formed by the resilient filamentary members. There is no disclosure of the interstices used for growing cells not being smaller. In line 15 of claim 1, after "inerstices", it is suggested that --- smaller than the interstices formed by the resilient filamentary members and --- be inserted. This insertion

should also be made in claim 10, line 17, after "interstices" with the omission of "and" at the end.

Claim Rejections - 35 USC § 112

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as
5 being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is confusing by not having clear antecedent basis for "said first named cell cultivation lattice" (bridging lines 2 and 3).

Claim Rejections - 35 USC § 102

10 Claims 1-3, 5-9, 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Thompson (5,718,159) for reasons set forth in the previous office action of 8/10/04.

The claims are drawn to a supported lattice for cultivating cells to form tissue containing the support substrate and a cell cultivation
15 lattice. The support substrate is formed of resilient filamentary members interlaced together to form relatively large interstices. The lattice is formed of flexible filamentary members interlaced with each other and the resilient filamentary members to form relatively small interstices.

20 Thompson discloses implantable prosthesis including stents and grafts intended for intraluminal fixation (col 1, lines 4-7). The prosthesis can be formed by interbraiding multiple structural strands with multiple textile strands (col 7, lines 14-20). The textile
stands (col 7, lines 40-60) are preferably multifilament yarns, but
25 can be monofilaments. The textile strands are 10-400 denier and can

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be made of polypropylene or polyethylene. The textile strands form a sheeting or fabric that is microporous. The structural strands can be stainless steel (col 6, line 24) or Elgiloy wire having a diameter of 0.0047 inches (0.12 mm), and braiding is no a mandrel (col 11, lines 5 48-53). Interstices between adjacent structural strands are occupied by textile sheeting or fabric formed by the textile strands (paragraph bridging cols 7 and 8 and Figures 5 and 6).

The prosthesis of Thompson has a structure as presently claimed and is encompassed by the present claims. The sheet or fabric of the 10 prosthesis is inherently capable of functioning for cultivating cells to form tissue.

Response to Arguments

Applicant's arguments filed 12/16/04 have been fully considered but they are not persuasive.

15 Applicants urge that Thompson discloses impermeability from layers that would not support cell growth. However, the present claims do exclude the impermeability disclosed by Thompson when a stent is formed. Cells could attach and grow on the outside of the members forming the interstices used for cell growth. The cells would 20 not have to be within the interstices, and the claims do not require the interstices adapted for growing cells to be large enough for cells to enter.

Claim Rejections - 35 USC § 103

Claims 4 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thompson in view of Vyakarnam et al (6,534,084 B1) for reasons in the previous office action.

5 Claim 4 requires the small interstices to be about 60-80 microns, and claim 17 requires the resilient and flexible filamentary members to comprise bio-absorbable material.

Thompson is described above.

10 Vyakarnam et al disclose bioabsorbable polymer foams (col 4, line 11) for implanting as a scaffold for cell growth for tissue regeneration. The foam can be a multiplayer tubular structure that allows regeneration of tissue that mimics the characteristics of blood vessels (col 9, lines 25-30). The structure can contain pores for cell invasion of a size of 80 Tm (col 6, line 46) or in a range of 80-
15 120 Tm (col 6, lines 28-29), or 60 Tm pores or in a range of 60-200 Tm (col 16, lines 8-10).

It would have been obvious to make the structural and textile strands of Thompson from a bioabsorbable polymer so the prosthesis will absorb into the body as suggested by Vyakarnam et al.

20 Additionally, it would have been obvious to provide the sheeting or fabric between the structural strands of Thompson with a pore size of 60-80 μ m as suggested by Vyakarnam et al for cell invasion.

Response to Arguments

Applicants urge that it is not obvious to combine the foam of Vyakarnam et al with the structural strands of Thompson. However, the rejection is not based on using the foam, but on using a bioabsorbable polymer used to make the foam and using the pore size of the foam to make the structural strands of Thompson. One can obviously provide the structure of Thompson using a bioabsorbable polymer and the foam pore size without producing the foam.

Claim Rejections - 35 USC § 102

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Stinson (5,891,191) for reasons in the previous office action.

The invention is described above.

Stinson discloses structure for a prosthesis including stents and stent grafts containing structural and textile strands essentially as disclosed by Thompson.

The prosthesis of Stinson has a structure as presently claimed and is encompassed by the present claims. The sheet or fabric of the prosthesis is inherently capable of functioning for cultivating cells to form tissue.

Response to Arguments

Applicants' argument concerning impermeability is unpersuasive for the type of reasons set forth above in regard to Thompson.

Claim Rejections - 35 USC § 103

Claims 5-9, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stinson in view of Thompson for reasons in the previous office action.

5 The claims require the resilient filamentary members to be monofilaments selected from stainless steel, nitinol and elgiloy monofilaments.

Thompson discloses that the structural strands can be stainless steel or Elgiloy wire.

10 It would have been obvious to use stainless steel or Elgiloy wire as the structural strands of Stinson as suggested by Thompson.

Response to Arguments

An argument responding to this rejection has not been made.

Claim Rejections - 35 USC § 103

15 Claims 4 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over stinson in view of Vyakarnam et al for reasons set forth above when rejecting these claims over Thompson in view of Vyakarnam et al for reasons in the previous office action.

Response to Arguments

20 Comments set forth above in responding to arguments concerning Vyakarnam et al also apply to this rejection.

Conclusion

Claims 10-12 and 14-16 are free of the prior art.

Applicant's amendment necessitated the new ground(s) of rejection
25 presented in this Office action. Accordingly, **THIS ACTION IS MADE**

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FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In
5 the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be
10 calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff
15 whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this
20 application or proceeding is assigned is 571-273-8300.

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5 from either Private PAIR or Public PAIR. Status information for
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10 9197 (toll-free).



David M. Naff
Primary Examiner
Art Unit 1651

DMN
3/21/05